

## Interim Report of the Minority Affairs Committee Meeting

November 29, 2011

Live Meeting Teleconference 11-2 EST

Silas P. Norman, MD, Chairman  
Meelie Debroy, MD, Vice-Chairman

### 1. Update on November 14-15 Board of Directors Meeting

Committee members were provided with a brief summary of relevant actions from the November 14-15, 2011 Board of Directors meeting in Atlanta, GA of interest to the Committee during its July 2011 meeting. The Committee was updated on the following:

- Board approval of modifications to multiple Policies and Bylaws requiring OPOs to perform a second ABO sub-typing test when a donor is identified as non-A<sub>1</sub> or non-A<sub>1</sub>B.
- Board approval of modifications to Policy 3.7.12.3 (Essential Information for Lung Offers) and 3.7.12.4 (Desirable Information for Lung Offers) for currency and readability, and adding non-contrast computed tomography (CT) scan of the chest to Policy 3.7.12.4.
- Board approval of modifications to Policy 3.7.6.3 (Candidate Variables in UNet<sup>SM</sup>) requiring transplant programs to update in no more than 14 days, any observed changes in certain clinical values most important to determining a candidate's Lung Allocation Score for high-LAS candidates.
- One year extension of the interim approval of modifications to Policy 3.7.3 (Adult Candidate Status), approved in November 2010 to December 1, 2012, permitting listings at Status 1A or 1B for outpatient adult candidates implanted with total artificial hearts.
- Board approval of modifications to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC) more clearly defining the imaging characteristics of HCC.
- Board approval of modifications to Policy 3.6 (Adult Donor Liver Allocation Algorithm) providing broader access to deceased donor organs for candidates awaiting a combined liver-intestine transplant.
- Board approval of a Committee-sponsored alternative allocation system for split liver allocation allowing a transplant center that accepts a right lobe for transplantation into a candidate on its list to transplant the left lobe/left-lateral segment into any other medically suitable patient listed at that institution or an affiliated pediatric institution.
- Board approval of modifications to Policies 5.10.1 (Vessel Recovery and Transplant) and 5.10.2 (Vessel Storage) restricting storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels when they are not transplanted during the original transplant procedure.

### 2. Educational Guidelines on Appropriate Patient Referral to Kidney Transplantation

The results of several recently completed MAC Committee survey projects demonstrated limited knowledge, understanding and awareness on the part of patients and referring providers alike, about patient options for transplantation, transplant processes in general, and opportunities for public input. In all three surveys, targeted education was identified as an area of need. As a result, the MAC *Subcommittee on Education and Awareness of Transplant Options* developed an educational initiative to improve patient access to transplantation by helping to raise awareness among physicians, practitioners, and their national societies about appropriate and timely patient referral to kidney transplantation. The goal of the initiative is to provide an opportunity for every medically eligible patient to be referred for transplant evaluation.

The initiative:

- Promotes the benefits of transplantation vs. dialysis as the default therapy for ESRD with a primary focus on preemptive transplantation.
- Promotes referral to transplantation for ALL patients with few exceptions. Final medical suitability will be determined by the individual transplant center following evaluation.
- Focuses on patients with Stage 4 and Stage 5 CKD.
- Promotes a GFR range to determine referral with a recommendation for optimum referral at (GFR =30) which aligns with currently published NKF Stage 4 and Stage 5 GFR ranges. All patients with a GFR of 30 should be approached to begin the conversation about transplantation to allow enough time for transplant education and the ability to locate a living donor for preemptive transplantation.
- Encourages provision of transplant education at recommended stages of CKD (GFR ranges) to correspond with the CMS reimbursed (MIPPA) transplant education program.
- Includes a FAQ section at the end of document.
- Provides facts supported by data on trends in transplantation/medical suitability for transplant to combat common myths among providers.
- Discusses specific barriers to transplantation for provider edification.
- Links to OPTN webpage for referring provider use in locating transplant center information.
- Recommends (voluntary) institution of a designated position (or an individual in a functional role) responsible for follow through of the referral process. The functional role would be broad enough to fit any number of job categories (dialysis nurse, social worker, etc.)

The Committee was updated on the *Subcommittee on Education and Awareness of Transplant Options* meeting on September 2011, to review the most recent draft of the guidelines document. Subcommittee members were assigned specific sections of the document to add, revise and expand. Each subcommittee member was also asked to provide 1-2 questions to contribute to the Frequently Asked Questions (FAQ) section. The Committee was also provided with a report on the changes to the document with a revised timeline. The draft will be released for full Committee review in mid-December with plan to finalize the document in early January. The expanded subcommittee meeting with other OPTN Committees and professional associations will be scheduled to occur soon thereafter. During discussion, Committee members commented positively on the progress of the document with a concern expressed that the document contained a significant amount of detail on post-referral processes. The document may be deviating from its primary focus of referral and some elements may be more appropriate for inclusion in a similar referral guidelines document targeted to patients.

### 3. Update on Development of a New Kidney Allocation System

The Committee was updated on progress toward development of a new proposed kidney allocation system. The Committee was informed that the system to allocate kidneys using an age matching formula (allocation to candidates + or – 15 years) has been construed as age discrimination by the federal government. Age may be used in an allocation formula as long as it is intended as a surrogate for a patient's medical condition and does not award priority on the basis of age alone. Subsequently, the Kidney Committee is reviewing modeling of concepts with the top 20% of kidneys allocated to patients with the highest estimated post transplant survival (EPTS) with the other proposed elements remaining in the formula (rank ordering for waiting /ESRD dialysis time, HLA DR matching, sliding score for panel reactive antibody (PRA) patients, the national variance transplanting A<sub>2</sub> and A<sub>2</sub>B kidneys into B candidates) and the addition of regional sharing.

The patients at the lower end of the EPTS score would be eligible to receive expedited placement for high KDPI kidneys (an improved expanded criteria donor (ECD) kidney model) and would consent in advance to receive these kidneys. For these patients, allocation would be based upon waiting time

using broader (regional) sharing for the most highly sensitized candidates. For OPO's in a region with shorter waiting times, kidneys procured within the DSA would not stay within the region but would first be offered out to patients in regions with longer waiting times. This is proposed to help reduce waiting time discrepancies due to geography. The Committee also reviewed simulation modeling results for the most recent run (Run 37) showing the number of transplants by age, race/ethnicity, ABO, diagnosis and PRA. Run 37 shows the following results compared to the current kidney allocation rules (Run 36) and those proposed in the concept document:

- Transplants to older age recipients (50-65+) decrease compared to the current rules but increase slightly as compared to the concept document.
- Transplants by race/ethnicity decrease slightly as compared to the current rules and the concept document.
- Transplants by ABO blood group are unchanged from both the current rules and the concept document.
- Transplants to diabetics decrease compared to the current rules, but increase as compared to the concept document.
- Transplants to highly sensitized patients decrease compared to the current rules but represent an increase compared to the concept document.

The Kidney Committee continues to discuss how to best accommodate very highly sensitized patients in the algorithm to improve the likelihood that high panel PRA patients receive an opportunity for an organ offer.

The Committee discussed the simulation results. Current models show no change by race and/or ethnicity as compared to the current system and a slight decrease in access to transplants as compared to the concept document. Members noted the loss of the small increase in transplants to minority candidates demonstrated in previous versions of the kidney allocation models. Though the increase was not large (3-5%) now there is no demonstrable improvement in access for minority candidates. Further, transplantation by ABO blood group is unchanged and with a decrease in transplants to patients with diabetes. These patients are disadvantaged in the model because their overall life span is shorter and many of these patients are minorities. Members commented on the fact that more benefit was not shown for minorities with the inclusion of dialysis time and the variance transplanting A<sub>2</sub>/A<sub>2</sub>B kidneys into B candidates in the model. It was suggested that the model may be reflecting the type of patients who are actually being placed on the waiting list since modeling is only able to demonstrate results using current behavior patterns. If provider behavior changes as a result of the new kidney allocation system and patients with longer waiting times gain access to the waiting list, then the numbers may improve.

The Kidney Committee is currently debating the amount of priority to assign to very highly sensitized candidates (98 %+). The Kidney Committee is attempting to determine the appropriate number of points to award patients who may only receive one organ offer a decade to allow them qualify for that organ, as compared to other candidates who may have other opportunities for offers.

The Committee also viewed slides summarizing the variance review process being undertaken by the Kidney Committee. It was proposed that there will be no changes in the system for approximately 18 months to two years. A member commented that the OPTN is not accepting any new applications for variances which would require programming.

#### 4. Review and Discussion of Public comment Proposals Distributed September 16, 2011

##### *1. Proposal to Clarify Requirements for Waiting Time Modification Requests (Kidney Transplantation Committee*

The Committee did not identify an inherent minority impact resulting from the proposal.

2. *Proposal to Extend the “Share 15” Regional Distribution Policy to “Share 15 National” (Liver and Intestinal Organ Transplantation Committee)*

The Committee discussed the liver proposals as a unit. The Committee did not identify any obvious minority impact as a result of the proposals but supported the concept of regional sharing in general as long as the concepts are executed as outlined in the proposal. The Committee noted that the proposals were reasonable as a start and represented the small incremental changes needed to improve geographic disparities in liver transplantation. The Committee expressed general concern with regard to broader sharing of livers and stressed the importance of the OPO metrics being used in conjunction with broader sharing to try to mitigate the “Center effect”, and in particular, the “OPO effect.” The Committee also suggested that the Liver Committee undertake a recurring analysis to determine if there are any unintended consequences as a result of the proposals (to include negative consequences for minority patients and controlling for the OPO effect)

3. *Proposal for Regional Distribution of Livers for Critically Ill Candidates (Liver and Intestinal Organ Transplantation Committee)*

The Committee discussed the liver proposals as a unit. The Committee did not identify any obvious minority impact as a result of the proposals but supported the concept of regional sharing in general as long as the concepts are executed as outlined in the proposal. The Committee noted that the proposals were reasonable as a start and represented the small incremental changes needed to improve geographic disparities in liver transplantation. The Committee expressed general concern with regard to broader sharing of livers and stressed the importance of the OPO metrics being used in conjunction with broader sharing to try to mitigate the “Center effect”, and in particular, the “OPO effect.” The Committee also suggested that the Liver Committee undertake a recurring analysis to determine if there are any unintended consequences as a result of the proposals (to include negative consequences for minority patients and controlling for the OPO effect)

4. *Plain Language Modifications to the Adult and Pediatric Heart Allocation Policies, Including the Requirement of Transplant Programs to Report in UNet<sup>SM</sup> a Change in Criterion or Status within Twenty-Four Hours of that Change (Thoracic Organ Transplantation Committee)*

The Committee did not identify an inherent minority impact resulting from the proposal.

5. *Proposed Revisions to and Reorganization of Policy 6.0 (Transplantation of Non-Resident Aliens), Which Include Changes to the Non-Resident Alien Transplant Audit Trigger Policy and Related Definitions (Ad Hoc International Relations and Ethics Committees)*

The Committee discussed the proposal at length and expressed primary concern with both the audit and reporting language as written in the policy. The Committee was concerned that the proposal did not define:

- (1) What would trigger an audit (1<sup>st</sup> non-resident alien transplant or the 100<sup>th</sup>?)
- (2) What the AHIRC Committee might be looking for in an audit
- (3) The details describing what might lead to punitive action

The MAC Committee was concerned that the lack of detailed information in the policy would leave transplant centers vulnerable. The Committee also expressed concern about the AHIRC independently and at its own discretion, auditing programs. A Committee review of transplant programs could be arbitrary and ill-defined, based on the changing composition of committee membership. The Committee also expressed concern about self-reported immigration status. The Committee is in favor of the data collection requirement approved by the Board. However, the Committee recommended that data be collected, reviewed and analyzed before any discussion of a review or audit takes place to first determine the scope of the problem (who is being transplanted and under what circumstances) and the threshold under which a review or audit might be

undertaken. The determination of an appropriate review of transplant centers might even be completed as part of a separate policy development effort. The Committee also cautioned against public reporting of data results without first reviewing and understanding the information and the resulting implications. The concern was that the information, if presented incorrectly, could be exploited and used for political opportunism under the current political environment.

With regard to a potential minority impact, a member noted that in Texas this would greatly impact minority patients because wealthy individuals from the Middle East are not seeking transplants, but individuals who have crossed the Mexican border into the US. These patients have access to immunosuppression and future medication and so they are transplantable. However, transplanting these patients would raise many flags for centers in Texas.

6. *Proposed Update to the Calculated PRA (CPRA) (Histocompatibility Committee)*

The Committee reviewed the proposal but had limited time in which to offer comment.

7. *Revision of the UNOS Bylaws, the OPTN Bylaws and the OPTN Policies that Govern HLA Laboratories (Histocompatibility Committee)*

The Committee reviewed the proposal but had limited time in which to offer comment.

8. *Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors (Living Donor Committee)*

The Committee reviewed the proposal but had limited time in which to offer comment. General comment was offered regarding the need to tie living donor follow up to reimbursement in order for it to be meaningful and for all transplant centers to become compliant.

9. *Proposal To Establish Minimum Requirements for Living Kidney Donor Follow-Up (Living Donor Committee).*

The Committee reviewed the proposal but had limited time in which to offer comment. General comment was offered regarding the need to tie living donor follow up to reimbursement in order for it to be meaningful and for all transplant centers to become compliant.

10. *Proposal to Establish Requirements for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)*

The Committee reviewed the proposal but had limited time in which to offer comment. General comment was offered regarding the need to tie living donor follow up to reimbursement in order for it to be meaningful and for all transplant centers to become compliant.

11. *Proposal to Eliminate the Use of an "Alternate" Label when Transporting Organs on Mechanical Preservation Machines and to Require the OPTN Distributed Standardized Label (Organ Procurement Organization (OPO) Committee)*

The Committee declined comment on the proposal.

12. *Proposal to Change the Term "Consent" to "Authorization" Throughout Policy When Used in Reference to Organ Donation (Organ Procurement Organization (OPO) Committee)*

The Committee declined comment on the proposal.

13. *Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions (Organ Procurement Organization (OPO) Committee)*

The committee declined comment on the proposal.

14. *Proposal to Clarify and Improve Variance Policies (Policy Oversight Committee (POC))*

The Committee declined comment on the proposal.

5. Minority Issues for Future Discussion

*Referral Survey to Assess Barriers to Thoracic Transplantation*

During the July meeting a MAC Committee member inquired about the possibility of launching a survey to assess barriers to Thoracic transplantation. It was noted that this appeared to be a logical next step for the Committee in its work identifying barriers to referral to transplantation

*Minority Donor Conversion Rates*

The MAC Committee previously reviewed data showing progress toward Health and Human Services (HHS) donor-related goals. The Committee had requested to be able to view results showing donor conversion rates by region and ethnicity; however, at the time OPOs were only required to provide monthly totals by donor hospital so this information was not available. The Donor Notification Registration (DNR) is now required on all imminent neurological and eligible deaths in the OPO's donor service area (DSA). This more detailed information is critical for analyzing donor conversion practices. Data on the distribution of donor conversion rates has been presented to the OPO Committee and to the AMAT and so the Committee requested to review data on donor conversion rates for different donor ethnic groups stratified by region for its March 2012 meeting.

The Committee will submit the two new proposed committee projects, the Thoracic Referral Survey and Minority Donor Conversion Rates during the next Executive Committee review cycle.

**ATTENDANCE FOR THE NOVEMBER 29, 2011**

**OPTN/UNOS MINORITY AFFAIRS COMMITTEE MEETING**

<b>Committee Members</b>	<b>Position</b>	<b>In Attendance</b>
Silas P. Norman, MD	Chair	Yes
Meelie A. Debroy, MD	Vice-Chair	Yes
Isabel Zacharias, MD	Region 1 Representative	Yes
Stacey H. Brann, MD	Region 2 Representative	No
Yma Waugh, MBA	Region 3 Representative	Yes
Sherilyn A. Gordon Burroughs, MD	Region 4 Representative	Yes
Ricardo Elizondo, RN, CPTC	Region 5 Representative	No
Stephen A. Kula, Ph.D, NHA	Region 6 Representative	Yes
Bruce A. King, MSW	Region 7 Representative	No
Antonio Sanchez, MD	Region 8 Representative	Yes
Lani V. Jones, PhD, MSW	Region 9 Representative	Yes
Asif A. Sharfuddin, MD	Region 10 Representative	No
Kelly C. McCants, MD	Region 11 Representative	No
Remonia A. Chapman, MD	At-Large	No
Pang-Yen Fan, MD	At-Large	Yes
Mohamed A. Hassan, MD	At-Large	Yes
Eddie Island, MD	At-Large	Yes
Maria R. Lepe, MD	At-Large	Yes
Rosaline Rhoden, MPH	At-Large	Yes
M. Christina Smith, MD	At Large	No
Karen A. Sullivan, Ph.D	At-Large	Yes

Henry B. Randall, MD	At-Large	Yes
Mesmin Germain, MBA, MPH	Ex-Officio, HRSA	Yes
Chinyere Amafulé	Ex-Officio, HRSA	No
<b>UNOS Staff</b>		
Deanna L. Parker, MPA	Committee Liaison/Minority Affairs Committee	Yes
Wida Cherikh, PhD	Sr. Research Biostatistician	Yes
<b>MMRF Staff</b>		
Monica M. Colvin Adams, MD	SRTR	Yes
Tabitha Leighton	SRTR	Yes
<b>Guests</b>		
Lee Bolton	Committee Liaison/Living Donor Committee	
Vipra Ghimire	Committee Liaison/Thoracic Organ Transplantation Committee and Ad Hoc International Relations Committee	
Lori Gore	Committee Liaison/Histocompatibility Committee	